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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,373	02/07/2006	Nobuaki Sumiyoshi	2005_1741A	3630

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WENDEROTH, LIND & PONACK, L.L.P.
1030 15th Street, N.W.,
Suite 400 East
Washington, DC 20005-1503

EXAMINER

KASSA, TIGABU

ART UNIT	PAPER NUMBER
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1619

MAIL DATE	DELIVERY MODE
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01/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/559,373</p>	<p>Applicant(s) SUMIYOSHI ET AL.</p>	
	<p>Examiner TIGABU KASSA</p>	<p>Art Unit 1619</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 December 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 16-21 and 23.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/YVONNE L. EYLER/
Supervisory Patent Examiner, Art Unit 1619

Continuation of 7 and 11. Applicants' remarks/arguments do not place the case in condition for allowance or in better condition for appeal. However, since applicants remarks/arguments do not overcome any of the rejections, applicants amendment will be entered.

Applicants traversed the rejections on the grounds that instant claims 16 and 19 are unobvious over the prior art references. Specifically, with regard to instant claim 16 Applicants assert that the potassium ion concentration of 0.0 to about 3.0 (mmol/L) taught by Segers et al. (US Patent 5383324) is a concentration after mixing a solution in the upper chamber with a solution in a lower chamber not the concentration of the potassium ion in each chamber. While asserting this feature Applicants also allege that the secondary reference (US Patent 6867193) does not disclose or suggest that the first solution and the second solution each have the same potassium salt, and the same potassium ion concentration of about 2 to 40 mEq/L as recited in claim 16. Therefore, those skilled in the art would not have arrived to the feature, wherein the first solution and the second solution each have a potassium ion concentration of about 2 to 40 mEq/L from Segers in view of Nakamura. The examiner respectfully disagrees with these assertions because Segers et al. clearly teach that in a preferred embodiment, the upper chamber 44 can further include sodium chloride, potassium chloride, dextrose and dextrose polymers. Likewise, the lower chamber 46 can further include sodium chloride, potassium chloride, amino acids, peptides and glycerol (column 7, lines 37-40). The examiner agrees with applicants that the concentration of the potassium ion taught by Segers et al. is the concentration after mixing the solutions in the upper and the lower chamber. However, the examiner respectfully disagrees with applicants' assertion that as written the claim limitation requires the same potassium ion concentration in each chamber because as long as the potassium ion concentration in each chamber lies within the instantly claimed range it does not have to be the same. Furthermore, the examiner takes the position that the concentration of the potassium ion in each chamber is not afforded patentability weight because Segers et al. clearly teach that potassium chloride is incorporated in both chambers even if Segers et al. is silent on the concentration of the potassium ion in each chamber. One of ordinary skill in the art clearly understands from the above teachings by Segers et al. that each chamber contributed some amount of potassium chloride. The examiner reminds applicants that a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). Additionally, a prima facie case of obviousness exists since differences in concentration, will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such features are critical, it is not inventive to discover the optimum or workable ranges by routine experimentation." on (see MPEP 2144.05 In re Aller, 220 F. 2d 454, 456, 105 USPQ 233,235 (CCPA 1955)). Furthermore, routine optimization of concentrations is prima facie obvious because it is within the purview of the skilled artisan. Applicant's arguments submitted regarding Nakamura et al., applicants are arguing against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The teachings of the incorporation of potassium salt in each chamber has been clearly taught by Segers et al. as described above and the concentration argument is rebutted as set forth above also. With regard to the unexpected effects achieved by the invention of instant claim 16, the examiner takes the position that the intended use applicants recite can also be achieved by the preparation taught by the prior art reference. Applicant relying upon comparative showing to rebut prima facie case must compare his claimed invention with closest prior art; conclusion that showing of superiority over prior art requires comparison between claimed invention and reference relied on by examiner is incorrect. *In re Holladay*, 584 F.2d 384, 199 USPQ 516 (CCPA 1978); *Ex parte Humber*, 217 USPQ 265 (Bd. App. 1961). Furthermore, Applicant, who neither established nor asserted that teachings of two closest prior art references are so parallel to one another that testing against one would show relative effectiveness of claimed invention over other, did not provide adequate basis to rebut conclusion of obviousness. *In re Johnson*, 747 F.2d 1456, 1461, 223 USPQ 1260, 1264 (Fed. Cir. 1984).

Applicants also asserted with regard to instant claim 19 that the osmotic pressure ratio disclosed by Nakamura et al. is the value after mixing the solution in the lower chamber and the solution in the upper chamber. This does not make sense because the examiner did not use the preparation example 2 as applicants argued in their citation for this part of the rejection. The examiner depend on the teaching of preparation example 1, wherein Nakamura et al. clearly teach that the albumin preparation which is the solution only in one chamber has the osmotic pressure ratio of 2.8 to 3.2 (column 5, lines 5-9). The arguments about the unexpected results are rebutted as described above

Similarly, Applicants also argued on the rejection of claim 16 under 35 U.S.C. 103(a) using Veech in view of Nakamura. Applicants assert that those skilled in the art would not have found it obvious for one chamber of a container to accommodate a parenteral solution, and at the same time the other chamber of the container to accommodate a peritoneal dialysis solution and the potassium ion concentration of 5 mM/L disclosed in Veech is not a concentration in each chamber, but a concentration after the contents of the chambers are combined and the solutions are mixed. The examiner respectfully disagrees with these assertions because, firstly, the examiner's rejection did not mention that one chamber contains a parenteral solution and the other chamber contains a peritoneal dialysis solution. The examiner just put in the record that Veech et al. teach exemplary solutions that can be incorporated in the chambers utilizing the preparation techniques taught in the disclosure of Veech et al. (column 6, lines 11-39). The examiner specifically brings applicants attention to Figures 1 and 2, wherein these embodiments contain two separate chambers. Applicants also argue that the potassium ion concentration of 5 mM/L disclosed in Veech is not a concentration in each chamber, but a concentration after the contents of the chambers are combined and the solutions are mixed. The examiner respectfully disagrees with this assertion because contrary to applicants' assertion this argument is not supported by the disclosure or claims of Veech et al. The examiner also requests for applicants to come on the record where in Veech et al. the potassium ion concentration of 5 mM/L is disclosed as the concentration of the solution after mixing. Similarly, applicants' argument with regard to Nakamura et al. in this section of the rejection is rebutted as set forth above. With respect to the unexpected effect applicants reciting the examiner takes the position that these effects are intended use. The examiner takes the position that the prior art structure is capable of performing the intended use, since structurally it is substantially similar to the instantly claimed invention. A recitation of the unexpected effect in the form of intended use it must be substantiated with an evidence that the claimed product has a structural difference with the prior art in order to patentably distinguish the claimed invention from the prior art. Applicant relying upon comparative showing to rebut prima facie case must compare his claimed invention with closest prior art; conclusion that showing of superiority over prior art requires comparison between claimed invention and reference relied on by examiner is incorrect. *In re Holladay*, 584 F.2d 384, 199 USPQ 516 (CCPA 1978); *Ex parte Humber*, 217 USPQ 265 (Bd. App. 1961). Furthermore, Applicant, who neither established nor asserted that teachings of two closest prior art references are so parallel to one another that testing against one would show relative effectiveness of claimed invention over other, did not provide adequate basis to rebut conclusion of obviousness. *In re Johnson*, 747 F.2d 1456, 1461, 223 USPQ 1260, 1264 (Fed. Cir. 1984). Applicants also argued about the rejection of instant claim 19 using Veech et al. in view of Nakamura et al. as they argued above for the different set of rejection using Segers et al. in view of Nakamura et al. Applicants also argued the

unexpected effect in the same way as set forth above. Those rebuttal arguments set forth above to address the rejections and the unexpected effect of the invention will also equally apply for this section of applicants' argument.

Applicants have not demonstrated how their product is patentably distinct from the cited prior arts nor do the claims as currently written distinguish the instant invention over the prior arts. In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.